

**REMARKS****Application Amendments**

The specification of Applicants' U.S. Patent Application, Publication No. 2002/0128704 (hereinafter "Specification"), has been amended to correct grammatical and typographical errors by replacing paragraphs [0002], [0004], [0006], [0007], [0011], [0015]- [0030] and [0032]- [0035].

Claims 1-8, and 10-23 have been amended, claim 9 has been canceled, and new claim 24 has been added. The amendments made to claims 1-8 and 10-23 were made to correct grammatical and/or typographical errors, to be in comport with claim terminology and guidelines, and to more clearly define the present invention. Claim 8 was also amended to change its dependency to claim 7.

Specifically, claims 1, 6, 11, 13-15, 20 and 21 were amended to more clearly define the implant/implant body/implantable member/implantable device as being capable of/being heated by exposure to an electromagnetic field having a frequency below about 1 MHz. The support for these amendments can be found throughout the Applicants' Specification and Claims as filed, U.S. Patent Application Publication No. 2002/0128704 (hereinafter "Specification"), particularly at paragraph [0035]. Support for new claim 24 can be found in the Specification at paragraph [0007]. No new matter has been added. Claims 1-8 and 10-24 are pending in the present application. Reconsideration of the claims is respectfully requested.

**Objection to Specification**

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter.

The Examiner asserts that the specification does not support the limitation in claim 1 that the drug material being only effective when heated by an exposure to an electromagnetic field. Claim 1 has been amended to reflect that the drug is effective when the implant body has been heated and that the implant body is heated by exposure to the electromagnetic field. Support for this amendment is found in the Specification at paragraphs [0016] and [0035].

The Examiner has objected to claim 9. Applicants have canceled claim 9 without prejudice.

The Examiner also asserts that the specification does not support the limitation in claim 16 that heating being invasive. Claim 16 is amended to reflect the non-invasive nature of the heating. Support for this amendment is found in the Specification at paragraphs [0006] and [0016].

### **Objection to Claims**

Claim 3 is objected to because of claim informality. The Examiner asserts that the phrase "where is substantially active" is missing words. Claim 3 is amended to include the missing words "the drug". Support for this amendment is found in the Specification at paragraphs [0007], [0010] and [0011].

### **Rejection under 35 U.S.C. § 101**

Claims 15-19 are rejected under 35 U.S.C. §101 because the claimed invention is purportedly directed to non-statutory subject matter. The Examiner asserts that claim 15 positively recites that the implantable member is implanted in the body, and that the patient's body is non-statutory subject matter. Claim 15 is amended to reflect that the apparatus comprises an implantable member and a drug, that the apparatus is for delivering the drug to a patient's body, and that the apparatus is capable of being implanted in a patient's body. Support for this amendment is found in the Specification at paragraphs [0031] and [0032]. Amended claim 15 and thus claims 16-19 thus have been appropriately amended.

### **Rejection under 35 U.S.C. § 102**

#### Sahatjian

The Examiner has rejected claims 13 and 15-23 under 35 U.S.C. §102 (b) as being anticipated by Sahatjian (US 5,304,121) (hereinafter "Sahatjian"). According to the Examiner, Sahatjian purportedly discloses a drug delivery catheter having either or both a balloon and/or stent coated with a drug material which when heated releases the drug to prevent restenosis.

Sahatjian discloses a catheter having a shaft and an expandable portion comprising a coating of a swellable hydrogel polymer that incorporates an aqueous mobile drug therein. The expansion of the expandable portion causes the drug to be delivered as the hydrogel polymer is compressed. Sahatjian also discloses that the expandable portion, which may comprise a stent, is

adapted such that the polymer material may be heated. The expandable portion may be a thermal balloon catheter with electrodes (col. 7, lines 48-49). The inflating liquid of the Sahatjian device may be heated as a result of  $I^2R$  losses by radio frequency current flowing in the inflation fluid between the electrodes, the liquid in turn heating the balloon wall (col. 9, lines 2-6).

By contrast, the implant/implant body/implantable member/implantable device of the present invention is capable of being heated "by exposure to an electromagnetic field having a frequency below about 1 MHz". Applicants submit that Sahatjian's device, which requires electrodes and thus utilizes direct current heating does not anticipate the Applicants' invention which involves inductive heating utilizing an electromagnetic field. Sahatjian does not disclose or suggest the use of an implant body that is capable of being heated by an electromagnetic field, wherein the field has a frequency below about 1 MHz. It is respectfully submitted that base claims 13, 15, 21, and their dependent claims 16-20 and 22-23 are now in condition for allowance, and that the Examiner's rejection should be withdrawn.

#### Rejection under 35 U.S.C. § 102 or § 103

##### Sahatjian / Diamantopoulos

The Examiner has rejected claims 1-8, 10-12 and 14 under 35 U.S.C. §102 (b) as being anticipated by Sahatjian, or in the alternative, under 35 U.S.C. §103 (a) as allegedly being obvious over Sahatjian in view of Diamantopoulos (EP 1 036 574) (hereinafter "Diamantopoulos"). According to the Examiner, Diamantopoulos purportedly discloses the use of electromagnetic fields to heat a stent. The Examiner contends that even though it is not disclosed, the endoprosthesis of Sahatjian, which is coated with the drug material would be capable of being released if heated by an electromagnetic field. Diamantopoulos also mentions the use of magnetic and electromagnetic types of radiation for heating the implants. The systems and methods disclosed in Diamantopoulos require the use of high frequency current (col. 2, lines 17-18 and col. 4, lines 5-6), such as 20 MHz (col. 2, lines 40-41).

By contrast, the presently claimed invention describes an implant/implantable device and methods of using said devices, wherein the device comprises an implant body and a drug material, wherein the implant body is capable of being heated by exposure to an electromagnetic field, wherein the field has a frequency of below about 1 MHz. The heating of the implant body, causes the drug material to heat, thereby providing an effective delivery vehicle for the drug material into

surrounding tissue. The implant/implant devices and methods of using said devices described in the present invention therefore relies on inductive heating principals.

Applicants submit that Sahatjian fails to disclose a non-invasive means for inductive heating of an implant for facilitating the delivery of a drug material. There is no evidence that the implant described in Sahatjian would be heated if an electromagnetic field of the recited frequency was applied to the Sahatjian implant. There is no suggestion that alternative energy sources or means may be applied to the implant described in Sahatjian. Additionally, Diamantopoulos fails to disclose an implant comprising a drug material, wherein the implant is heated by exposure to an electromagnetic field having a frequency below 1 MHz, to deliver a drug material. Diamantopoulos supplies no motivation or suggestion that alternative frequencies may be used, or that inductive heating may be used in a drug/implant combination. Therefore, the motivation to combine the references as suggested by Examiner is specifically lacking.

The disclosures of Sahatjian and Diamantopoulos, whether alone or in combination, do not teach, motivate or suggest the Applicants' claims, as amended, for an implant, heated by exposure to an electromagnetic field having a frequency below 1 MHz, to deliver a drug material or to activate/deactivate the action of a drug, or for methods of using said implant.

As the references cited by the Examiner, individually or their proposed combination, fail to teach all the elements of Applicants' base claims 1, 6, 11 and 14 as amended, and their dependent claims 2-8, 10 and 12, it is respectfully submitted that these claims are now in condition for allowance, and that the Examiner's rejection should be withdrawn.

### Rejection under 35 U.S.C. § 103

#### Yang / Rosenthal or Diamantopoulos or Günther

The Examiner has rejected claims 1-8 and 10-23 under 35 U.S.C. §103 (a) as being unpatentable over Yang (US 6,379,382) (hereinafter "Yang") in view of Rosenthal et al. (US 6,524,274) (hereinafter "Rosenthal"), Diamantopoulos or Günther (US 6,238,421) (hereinafter "Günther").

Applicants submit that Günther is disqualified as a prior art basis for this rejection because Günther is a commonly owned reference, and it was commonly owned (via an assignment) at the time of Applicants' invention. (MPEP 706.02(l)(2) and 35 U.S.C. § 103(b)(1)(B)).

According to the Examiner, Yang purportedly discloses a coated stent with drugs therein which are released over time, Rosenthal purportedly discloses that it was known to provide a coating with drugs therein having a melting point above body temperature which can be heated to cause the release of the drugs, and Günther purportedly discloses the use of electromagnetic fields to heat a stent. The Examiner asserts that it would have been obvious to have used the magnetic fields taught by Diamantopoulos or Günther to heat the coated stent of Yang.

Yang discloses a prosthesis comprising a stent and a cover about the periphery of the stent, said cover having at least one chamber defined by at least two layers of materials with at least one layer being permeable to drugs. A drug can be loaded into at least one chamber or into the material of one of the layers. The drug is released over a period of time after the prosthesis is implanted inside the desired vessel. Although Yang discloses various means for the delivery of the drug to the desired vessel or tissue, such as diffusion, via perforations or holes, and ionic interaction, Yang fails to disclose, teach or suggest the use of any external energy source, such as an electromagnetic field at the recited frequency to facilitate drug delivery. Therefore, the prosthesis of Yang is not capable of being heated by exposure to a magnetic field at the recited frequency.

Rosenthal discloses a thermal catheter comprising a catheter shaft having an expandable balloon portion coated with a temperature-sensitive hydrogel previously loaded with a drug. Upon the placement of the catheter in a body, the balloon portion is expended and heat is applied to the hydrogel coating. An increase of at least 1°C above the ambient body temperature triggers the release of the drug by inducing a volume phase transition of the hydrogel (col. 4, lines 4-8 and col. 10, lines 6-10). Although Rosenthal discloses heating via a fiber optic device as a local heat source and heating as a result of  $I^2R$  losses by radio frequency current flowing in the inflating fluid (of the catheter balloon) between the electrodes of the thermal catheter, Rosenthal fails to disclose, teach or suggest inductive heating utilizing electromagnetic fields.

Diamantopoulos discloses non-invasive means of heating metallic implants, such as stents. Diamantopoulos also mentions the use of magnetic and electromagnetic types of radiation for heating the implants. The systems and methods disclosed in Diamantopoulos require the use of high frequency current, such as 20 MHz.

Applicants submit that neither Rosenthal nor Diamantopoulos cures the deficiencies of Yang to arrive at the Applicants' claimed invention. As the proposed combinations of references

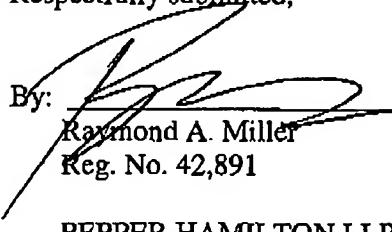
cited by the Examiner fail to teach all the elements of Applicants' base claims 1, 6, 11, 13-15, 20 and 21, as amended, Applicants respectfully submit that claims 1, 6, 11, 13-15, 20 and 21 are now in condition for allowance and that the Examiner's rejection should be withdrawn. Claims 2-5, 7-8, 10, 12, 16-19 and 22-23, which depend from claims 1, 6, 11, 15 and 21 are now also in condition for allowance as they depend from the previously rejected base claims. It is respectfully submitted that the Examiner's rejection of these claims also be withdrawn.

In view of the amendments and remarks presented hereinabove, Applicants believe that pending claims 1-8 and 10-24 are in condition for allowance and notice to such effect is respectfully requested. Although Applicants believe no fees are due, the Commissioner is hereby authorized to charge deposit account No. 50-0436 for any fees that may be due in connection with this response. Should the Examiner have any questions regarding these remarks, the Examiner is invited to initiate a telephone conference with the undersigned.

Respectfully submitted,

Date: November 30, 2004

Respectfully submitted,

By:   
Raymond A. Miller  
Reg. No. 42,891

PEPPER HAMILTON LLP  
500 Grant Street  
One Mellon Bank Center, 50<sup>th</sup> Floor  
Pittsburgh, PA 15219  
(412) 454-5813  
(412) 281-0717 - facsimile